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JOHN L. PITTS, D.V.M.
Aquaculture/Aquatic Animal Health

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copy MUMS group
original to Docket 97N-0217

Dr. Steve Sundlof, Director,
Office of the Director, HFV-1
U.S. FDA, Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I want to thank you and your staff for all of the time and effort that you have spent over the past few years dealing with aquatic animal species drug approvals. Most recently, the leadership that CVM has taken in the Animal Drug Availability Act and its interaction with minor species industries, is testimony to your agencies sincere concern for the health and welfare of animals and the protection of human health.

I strongly support the ADAA Draft Discussion Document and hope that CVM's submission to Congress parallels that draft. I believe that the Alternative Approval Standard and Expert Review Panel for non-food animals is an excellent approach to drug approvals in animals that pose little or no risk to the health of humans. This proposed process is workable and affordable, and will provide the needed information for drug approvals for non-food animals. While I can understand why minor species food animal producers would like to use this mechanism for drug registration, I am concerned that the inclusion of food animals in this section of the ADAA submission to Congress is premature. The deviation from the existing Food, Drug and Cosmetic Act allowing Alternate Standards and Expert Review for food animals could meet with opposition from consumer groups concerned about tissue residues in food resulting from a novel drug approval approach. Please limit the Alternative Standards and Expert Panels process to non-food animal drug products, but provide an option for review of this process in 3-5 years. Non-food animal products' manufacturers could meet with FDA/CVM and food animal drug manufacturers to explore the progress of drug approvals under Alternate Standards and develop a strategy to include minor food animal species in the process where applicable. With a positive non-food animal drug approval experience, it may be more reasonable to expect that minor species food animal drug approvals could also utilize new alternative standards in the future.

Sincerely,

John L. Pitts, DVM

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